

MEMORANDUM OF MEETING

Rec'd 9/30/04

Date: Wednesday, June 16, 2004

Place: Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN), Harvey W. Wiley Federal Building, College Park, MD

Participants:

California Fine Wine Alliance

Emanuel Berk, The Rare Wine Co.
Louis Dupart, Fleishman and Walsh, LLP
Stuart Pape, Patton Boggs, LLP
Jamie Ritchie, Sotheby's

Congressman Henry Bonilla's Office

Walt Smith

Food and Drug Administration

Leslye Fraser, Center for Food Safety and Applied Nutrition (CFSAN)
L. Robert Lake, CFSAN
Larry Lazarus, Office of the Commissioner
Stacy McBride, Office of the Commissioner
Joseph McCallion, Office of Regulatory Affairs
David Mednick, Office of General Counsel
May Nelson, CFSAN

Subject: Prior Notice of Imported Food Interim Final Rule

The California Fine Wine Alliance ("Fine Wine Alliance") requested a meeting with FDA to discuss how the prior notice requirements impact the fine wine industry.

The Fine Wine Alliance made the following points:

- The fine wine importers request an exemption from prior notice requirements for the manufacturer's registration number. Due to the nature of the fine wine trade, fine wine importers may not have access to the manufacturer's registration number. Any shipment eligible for an

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exemption or special handling only would involve manufacturers from FDA-registered facilities.

- In lieu of the manufacturer's registration number, the fine wine importer would be willing to provide the name and address of the manufacturing facility in the prior notice submission. The importer also would affirm that to the best of its knowledge, the facility is in fact registered. The fine wine importer would have confidence that the facility is in fact registered because fine wine only is produced by limited number of producers, and importers are familiar with each manufacturer and whether the manufacturer is registered.
- The fine wine industry is unique. The allocation of fine wine is distributed by country. If there is more demand in one country, brokers can meet demand by shifting product from another country where supply is not as high. It is common practice to age fine wine. Thus, the fine wine can be stored for many years after production before it goes into distribution. It is also common for fine wine to change hands multiple times before it reaches the consumer.
- There are only a relatively small number of fine wine importers—maybe 100 at best. Fine wine importers are permitted by the Alcohol and Tobacco Tax and Trade Bureau (TTB). The TTB conducts background checks, fingerprint checks, and other types of investigations before the importer will be allowed to conduct business.
- Most fine wine shipments arrive in the U.S. by boat to a handful of ports (CA/NY/MD).
- If FDA allowed fine wine importers to provide the name and address of the manufacturer in lieu of the manufacturer's registration number, the fine wine importers would be willing to submit prior notice in a timeframe that allows FDA more time to review the prior notice submission. The fine wine importers also would be amenable to providing FDA with a database containing the names and addresses of fine wine producers.
- If FDA does not develop a solution for the fine wine industry, domestic companies may relocate to Canada and a black market for fine wine may develop.

In response to these points, FDA asked the Fine Wine Alliance to submit comments to the docket that address the following points:

- How are the fine wine importers already regulated by other agencies?
- What other assurances can be provided to give FDA confidence that the fine wine being imported is from a registered facility and that the information provided relates to the specific facility that manufactured the wine being imported or offered for import?